

Notice of Allowability

Application No.

09/077,572

Applicant(s)

APICELLA ET AL.

Examiner

Art Unit

S. Devi, Ph.D.

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendments filed 04/27/05 and 02/27/05.
2. ☒ The allowed claim(s) ~~is/are~~ 37, 37 and 39, now renumbered as claims 1, 2 and 3 respectively.
3. ☒ The drawings filed on 14 June 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 11/1/04 (Figures 4-7).
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☒ Other Attachment.

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ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendments

- 1) Acknowledgment is made of Applicants' amendments filed 09/23/04, 02/07/05 and 04/27/05 in response to the non-final Office Action mailed 12/09/03.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Ann S. Viksnins in a telephonic interview on 27 April 2005.

This application has been amended as indicated below:

- (a) Claim 38 has been canceled.
(b) Claim 37 has been replaced with the following:

-- Claim 37. (Currently amended) A purified conjugate of a mutant endotoxin from an *htrB* mutant of non-typeable *Haemophilus influenzae* conjugated to a carrier protein, wherein the mutant endotoxin contains a decreased phosphoethanolamine content and an increased hexose content in the mutant endotoxin's inner core and a pentaacylated or tetraacylated lipid A lacking one or more secondary acyl chains compared to the corresponding wild-type non-typeable *Haemophilus influenzae* hexaacylated endotoxin, and wherein the mutant endotoxin has substantially reduced toxicity as compared to the hexaacylated endotoxin of the wild-type non-typeable *Haemophilus influenzae*.--

- (c) New claim 39 has been added as indicated below:

-- Claim 39. (New) A method for preparing a conjugate of a mutant endotoxin from an *htrB* mutant of non-typeable *Haemophilus influenzae*, wherein the mutant endotoxin contains a decreased phosphoethanolamine content and an increased hexose content in the mutant endotoxin's inner core and a pentaacylated or tetraacylated lipid A lacking one or more secondary acyl chains compared to the corresponding wild-type non-typeable *Haemophilus influenzae* hexaacylated endotoxin, and wherein the mutant endotoxin has substantially reduced toxicity as compared to the corresponding wild-type non-typeable *Haemophilus influenzae* hexaacylated endotoxin, said

method comprising purifying the mutant endotoxin by phenol water extraction or protease digestion and conjugating the purified mutant endotoxin to a carrier protein.--

Status of Claims

- 3) Claims 22 and 27-33 have been amended via the amendment filed 02/07/05.
Claims 23-26 and 35 have been canceled via the amendment filed 04/27/05.
New claims 37 and 38 have been added via the amendment filed 04/27/05.
Claim 38 has been canceled via this Examiner's amendment.
New claim 39 has been added via this Examiner's amendment.
Claims 36, 37 and 39 are pending and are under examination.

Terminal Disclaimer

- 4) Acknowledgment is made of Applicants' submission of a terminal disclaimer filed 02/07/05 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of the US patent 6,887,483.

Amendment/Petition under 37 C.F.R § 1.48(b)

- 5) Acknowledgment is made of Applicants' amendment/petition filed 06/14/04 under 37 C.F.R § 1.48(b) requesting correction of inventorship by deleting Rasappa Arumugham as an inventor of the instant application. No new oath/declaration was filed along with the petition to correct inventorship. This petition is however moot now in view of Applicants' request to reinstate Rasappa Arumugham as an inventor due to Applicants' addition of new claims. See page 5 of the amendment filed 04/27/05. The original oath/declaration signed by all inventors including Rasappa Arumugham is of record and no new oath/declaration is needed.

Drawings

- 6) The formal drawings for Figures 1-3 filed 06/14/04 have been accepted. However, it is noted that Applicants are yet to submit acceptable drawings for Figures 4-7.

Rejection(s) Moot

- 7) The rejection of claims 22, 23, 25 and 29 made or maintained in paragraph 9 of the Office Action mailed 04/28/99, paragraph 11 of the Office Action mailed 04/03/03 and paragraph 22 of the Office Action mailed 12/09/03 under the judicially created provisional obviousness type double

patenting over the cited claim(s) of application SN 09/565,943, is moot in light of Applicants' cancellation of the claims.

- 8)** The rejection of claim 22 under paragraphs 23(a) and 23(b) of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 9)** The rejection of claim 22 under paragraph 23(c) of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 10)** The rejection of claim 23 under paragraph 23(d) of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 11)** The rejection of claim 29 under paragraph 23(e) of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 12)** The rejection of claim 29 under paragraph 23(f) of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 13)** The rejection of claims 23-26, 32 and 33 made paragraph 23(g) of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the base claim.
- 14)** The rejection of claims 22-26 and 32 made paragraph 24 of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.
- 15)** The rejection of claims 22-26, 29, 32 and 33 made paragraph 25 of the Office Action mailed 12/09/03 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.
- 16)** The rejection of claims 22-26, 29, 32 and 33 made paragraph 26 of the Office Action mailed 12/09/03 under 35 U.S.C. 112, first paragraph, as being non-enabled with regard to the scope, is

moot in light of Applicants' cancellation of the claims.

Remarks

17) Claims 36, 37 and 39, now renumbered as claims 1-3 respectively, are allowed.

The descriptive support for the limitation added to claim 37 via this Examiner's amendment is found at lines 9-11 on page 10 of the specification. The new independent claim 39 has descriptive support at pages 7-10 of the specification and the original claims 23 and 27.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of after-final amendments is (703) 872-9306.

19) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed the Group receptionist whose telephone number is (571) 272-1600.

April, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER